JAN 17 2012

MAQUET
GETINGE GROUP

510(k) Summary
(as required by 21 CFR 807.92)

510(k) Number: K113101

Date Prepared: November 28, 2011

Device Owner: MAQUET Cardiovascular LLC
45 Barbour Pond Drive
Wayne, New Jersey 07470

Contact Personnel: Susan Eichler-Huston
Title: Director, Regulatory Affairs
Email: susan.eichler-huston@maquet.com
Phone: 973-709-7487 **Fax:** 973-709-6522

Trade Name: EXXCEL™ Soft ePTFE Vascular Grafts

Device Generic Name: Vascular Graft Prosthesis

Classification: According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Device: EXXCEL™ Soft ePTFE Vascular Grafts

Device Description: EXXCEL™ Soft ePTFE Vascular Grafts are synthetic vascular grafts constructed of expanded polytetrafluoroethylene (ePTFE). EXXCEL™ Soft ePTFE Vascular Grafts feature a GUIDELINE® stripe to facilitate proper graft alignment.

Indications for Use: Standard Wall EXXCEL™ Soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries (iliac, femoral, popliteal, infrageniculate vessels, axillary, renal) and to provide vascular access. Thin Wall Exxcel™ Soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries (iliac, femoral, popliteal, infrageniculate vessels, axillary, renal).

Technological Characteristics The proposed Exxcel Soft ePTFE Vascular Graft and the predicate Exxcel Soft ePTFE Vascular Graft are similar with respect to the following:

- Equivalent finished device characteristics
- Equivalent indication for use
- Equivalent packaging, sterilization and shelf life

The proposed Exxcel Soft ePTFE Vascular Graft and the predicate Exxcel Soft ePTFE Vascular Graft, are different

with respect to the following:

- The proposed device utilized a PTFE resin manufactured using a non-PFOA surfactant as a process aid.

This difference is not considered a technological difference and is substantially equivalent to the predicate Exxcel Soft ePTFE Vascular Graft.

Safety and Performance:

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The device was qualified through the following tests:

- Kink Diameter
- Longitudinal Tensile Strength
- Wall Thickness
- Oblique Suture Retention Strength
- Longitudinal Suture Retention Strength
- Relaxed Internal Diameter
- Usable Length
- Water Entry Pressure (WEP)
- Radial Burst Strength (Burst Pressure)
- Strength After Repeated Puncture
- Pressurized Internal Diameter
- Biocompatibility Testing
    - Cytotoxicity
    - Hemolysis

The results of these non-clinical tests met the specified acceptance criteria and were substantially equivalent to the predicate device.

No new safety or performance issues were raised during the testing regimen.

Conclusion:

Based on the Indication for Use, technological characteristics and safety and performance testing, the EXXCEL™ Soft ePTFE Vascular Graft has been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 17 2012

MAQUET Cardiovascular LLC
c/o Ms. Susan Eichler-Huston
Director, Regulatory Affairs
45 Barbour Pond Drive
Wayne, NJ 07470

Re: K113101
Trade/Device Name: EXXCEL Soft ePTFE Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II (two)
Product Code: DSY
Dated: October 14, 2011
Received: October 19, 2011

Dear Ms. Eichler-Huston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K113101

Device Name: EXXCEL™ Soft ePTFE Vascular Graft

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113101

__X__ Prescription Use
(Per 21 CFR 801.109)

OR

___Over-The-Counter Use
(Optional Format 1-2-96)